



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	2126.R0
True Name	Borrelia Burgdorferi Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	<i>Borrelia burgdorferi</i>
Study Purpose	Demonstrate efficacy against disease caused by <i>Borrelia burgdorferi</i>
Product Administration	Subcutaneously (SQ)
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 27, 1995

Study Type	Efficacy
Pertaining to	<i>Borrelia burgdorferi</i>
Study Purpose	Demonstrate efficacy against <i>Borrelia burgdorferi</i> 12 months after vaccination to establish a minimum duration of immunity
Product Administration	Subcutaneously (SQ)
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 15, 1996

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions.
Product Administration	Subcutaneously (SQ)
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 12, 1996